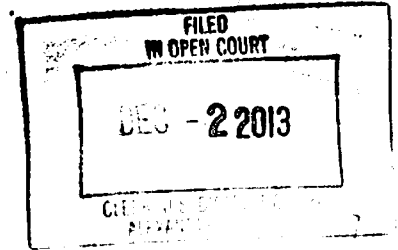


IN THE UNITED STATES DISTRICT COURT FOR THE  
EASTERN DISTRICT OF VIRGINIA  
Alexandria Division



UNITED STATES OF AMERICA )

v. )

GALLANT PHARMA INTERNATIONAL, INC., )

Defendant. )

CRIMINAL NO. 1:13-cr-130-1

Hon. Claude M. Hilton

PLEA AGREEMENT

Dana J. Boente, Acting United States Attorney for the Eastern District of Virginia;  
Lindsay A. Kelly, Assistant United States Attorney; the defendant, GALLANT PHARMA  
INTERNATIONAL INC. ("GALLANT PHARMA"), by and through its undersigned attorneys,  
and through its authorized representative, have entered into an agreement pursuant to Rule 11 of  
the Federal Rules of Criminal Procedure. The terms of the agreement are as follows:

**1. Offense and Maximum Penalties**

The defendant agrees to plead guilty to:

- (a) Counts 2 and 3 of the Indictment, charging the defendant with Importation Contrary to Law, in violation of Title 18, United States Code, Section 545;
- (b) Counts 4-8 of the Indictment, charging the defendant with Introducing Misbranded Drugs Into Interstate Commerce, in violation of Title 21, United States Code, Section 331(a); and
- (c) Counts 9-13 of the Indictment, charging the defendant with Unlicensed Wholesale Distribution of Prescription Drugs, in violation of Title 21, United States Code, Section 331(t).

The maximum penalties for a violation of 18 U.S.C. § 545 by a corporation are a fine of \$500,000 or twice the gross gain or loss from the offense, full restitution, a \$400 special assessment, and five (5) years of probation.

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The maximum penalties for a violation of 21 U.S.C. § 331(a) by a corporation are a fine of \$10,000, full restitution, and a \$400 special assessment.

The maximum penalties for a violation of 21 U.S.C. § 331(t) by a corporation are a fine of \$250,000, full restitution, and a \$400 special assessment.

**2. Factual Basis for the Plea**

The defendant will plead guilty because the defendant is in fact guilty of the charged offenses. The defendant admits the facts set forth in the statement of facts filed with this plea agreement and agrees that those facts establish guilt of the offense charged beyond a reasonable doubt. The statement of facts, which is hereby incorporated into this plea agreement, constitutes a stipulation of facts for purposes of Section 1B1.2(a) of the Sentencing Guidelines.

**3. Agreement Contingent Upon Plea of Co-Defendant**

The defendant understands and agrees that the promises of the United States in this plea agreement are expressly contingent upon the guilty plea of co-defendant SYED HUDA (a/k/a “Farhan Huda”) to Counts 2, 4, 13, and 14 of the Indictment. The defendant understands and agrees that should co-defendant SYED HUDA’s guilty plea not be accepted by the Court, the United States, at its sole option, will be released from its obligations under the plea agreement. The defendant likewise understands and agrees that, should the pleas of co-defendants SYED HUDA or TALIB KHAN later be withdrawn for any reason, or should either co-defendant fail to appear at sentencing, or should either co-defendant fail to report or to surrender at any time as directed by the Court, the United States, at its sole option, will be released from its obligations under the plea agreement. The defendant understands and agrees that any such event may be treated as if it were a breach of this agreement by the defendant, and all of the remedies provided in this agreement in the event of a breach shall be available to the United States.

**4. Assistance and Advice of Counsel**

The defendant is satisfied that the defendant's attorney has rendered effective assistance. The defendant understands that by entering into this agreement, defendant surrenders certain rights as provided in this agreement. The defendant understands that the rights of criminal defendants include the following:

- a. the right to plead not guilty and to persist in that plea;
- b. the right to a jury trial;
- c. the right to be represented by counsel – and if necessary have the court appoint counsel – at trial and at every other stage of the proceedings; and
- d. the right at trial to confront and cross-examine adverse witnesses, to be protected from compelled self-incrimination, to testify and present evidence, and to compel the attendance of witnesses.

**5. Role of the Court and the Probation Office**

The defendant understands that the Court has jurisdiction and authority to impose any sentence within the statutory maximum described above but that the Court will determine the defendant's actual sentence in accordance with Title 18, United States Code, Section 3553(a). The defendant understands that the Court has not yet determined a sentence and that any estimate of the advisory sentencing range under the U.S. Sentencing Commission's Sentencing Guidelines Manual the defendant may have received from the defendant's counsel, the United States, or the Probation Office, is a prediction, not a promise, and is not binding on the United States, the Probation Office, or the Court. Additionally, pursuant to the Supreme Court's decision in *United States v. Booker*, 543 U.S. 220 (2005), the Court, after considering the factors set forth in Title 18, United States Code, Section 3553(a), may impose a sentence above or below the advisory sentencing range, subject only to review by higher courts for reasonableness. The

United States makes no promise or representation concerning what sentence the defendant will receive, and the defendant cannot withdraw a guilty plea based upon the actual sentence.

Further, in accordance with Rule 11(c)(1)(B) of the Federal Rules of Criminal Procedure, the United States and the defendant will recommend to the Court that the following provisions of the Sentencing Guidelines apply:

- a. The fine amount will be determined by Section 8C1.1 because the organization operated primarily for a criminal purpose or primarily by criminal means (U.S.S.G. § 8A1.2(b)(1)).

The United States and the defendant will further recommend to the Court that the \$3.4 million forfeiture money judgments imposed on co-defendants TALIB KHAN and SYED HUDA, to be fulfilled by the repatriation and forfeiture of assets under the direct or indirect control of TALIB KHAN and/or SYED HUDA, will be sufficient to divest GALLANT PHARMA of all its net assets.

#### **6. Waiver of Appeal, FOIA, and Privacy Act Rights**

The defendant also understands that Title 18, United States Code, Section 3742 affords a defendant the right to appeal the sentence imposed. Nonetheless, the defendant knowingly waives the right to appeal the conviction and any sentence within the statutory maximum described above (or the manner in which that sentence was determined) on the grounds set forth in Title 18, United States Code, Section 3742 or on any ground whatsoever, in exchange for the concessions made by the United States in this plea agreement. This agreement does not affect the rights or obligations of the United States as set forth in Title 18, United States Code, Section 3742(b). The defendant also hereby waives all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation

any records that may be sought under the Freedom of Information Act, Title 5, United States Code, Section 552, or the Privacy Act, Title 5, United States Code, Section 552a.

**7. Special Assessment**

Before sentencing in this case, the defendant agrees to pay a mandatory special assessment of four hundred dollars (\$400.00) per count of conviction.

**8. Payment of Monetary Penalties**

The defendant understands and agrees that, pursuant to Title 18, United States Code, Section 3613, whatever monetary penalties are imposed by the Court will be due immediately and subject to immediate enforcement by the United States as provided for in Section 3613. Furthermore, within 14 days of a request, the defendant agrees to provide all of the defendant's financial information to the United States and the Probation Office and, if requested, to participate in a pre-sentencing debtor's examination and/or complete a financial statement under penalty of perjury. If the Court imposes a schedule of payments, the defendant understands that the schedule of payments is merely a minimum schedule of payments and not the only method, nor a limitation on the methods, available to the United States to enforce the judgment.

**9. Restitution**

Defendant agrees that restitution is mandatory pursuant to 18 U.S.C. §3663A. Defendant agrees to the entry of a Restitution Order for the full amount of the victims' losses. Pursuant to 18 U.S.C. § 3663A(c)(2), the defendant agrees that an offense listed in § 3663A(c)(1) gave rise to this plea agreement and as such, victims of the conduct described in the charging instrument, statement of facts or any related or similar conduct shall be entitled to restitution. The government is currently aware that the following entities are victims of these offenses: Allergan,

AmGen, AstraZeneca, Eli Lilly & Co., Genentech, the Internal Revenue Service, Medicis, Millennium Pharmaceuticals, Novartis, and Sanofi-Aventis.

**10. Immunity from Further Prosecution in this District**

The United States will not further criminally prosecute the defendant in the Eastern District of Virginia for the specific conduct described in the Indictment or statement of facts, including the tax liability issues that have been disclosed during this investigation.

**11. Dismissal of Other Counts**

As a condition of the execution of this agreement and the Court's acceptance of the defendant's plea of guilty, the United States will move to dismiss the remaining counts of the Indictment against this defendant.

**12. Payment of Taxes and Filing of Tax Returns**

The defendant consents to any motion by the United States under Rule 6(e)(3)(E) of the Federal Rules of Criminal Procedure, to disclose grand jury material to the Internal Revenue Service for use in computing and collecting the defendant's taxes, interest and penalties, and to the civil and forfeiture sections of the United States Attorney's Office for use in identifying assets and collecting fines and restitution. The defendant also agrees to file true and correct tax returns for the years 2009-2012 within one hundred twenty (120) days and to pay all taxes, interest and penalties for the years 2009-2012 within a reasonable time in accordance with a plan to be devised by the Probation Office. The defendant further agrees to make all books, records and documents available to the Internal Revenue Service for use in computing defendant's taxes, interest and penalties for the years 2009-2012.

### **13. Breach of the Plea Agreement and Remedies**

This agreement is effective when signed by the defendant (through its authorized representative), the defendant's attorney, and an attorney for the United States. The defendant agrees to entry of this plea agreement at the date and time scheduled with the Court by the United States (in consultation with the defendant's attorney). If the defendant withdraws from this agreement, or commits or attempts to commit any additional federal, state or local crimes, or otherwise violates any provision of this agreement, then:

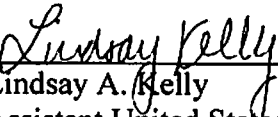
- a. The United States will be released from its obligations under this agreement. The defendant, however, may not withdraw the guilty plea entered pursuant to this agreement;
- b. The defendant will be subject to prosecution for any federal criminal violation, including, but not limited to, perjury and obstruction of justice, that is not time-barred by the applicable statute of limitations on the date this agreement is signed. Notwithstanding the subsequent expiration of the statute of limitations, in any such prosecution, the defendant agrees to waive any statute-of-limitations defense; and
- c. Any prosecution, including the prosecution that is the subject of this agreement, may be premised upon any information provided, or statements made, by the defendant, and all such information, statements, and leads derived therefrom may be used against the defendant. The defendant waives any right to claim that statements made before or after the date of this agreement, including the statement of facts accompanying this agreement or adopted by the defendant and any other statements made pursuant to this or any other agreement with the United States, should be excluded or suppressed under Fed. R. Evid. 410, Fed. R. Crim. P. 11(f), the Sentencing Guidelines or any other provision of the Constitution or federal law.

Any alleged breach of this agreement by either party shall be determined by the Court in an appropriate proceeding at which the defendant's disclosures and documentary evidence shall be admissible and at which the moving party shall be required to establish a breach of the plea agreement by a preponderance of the evidence.

**14. Nature of the Agreement and Modifications**

This written agreement constitutes the complete plea agreement between the United States, the defendant, and the defendant's counsel. The defendant (through its authorized representative) and the defendant's attorney acknowledge that no threats, promises, or representations have been made, nor agreements reached, other than those set forth in writing in this plea agreement, to cause the defendant to plead guilty. Any modification of this plea agreement shall be valid only as set forth in writing in a supplemental or revised plea agreement signed by all parties.

Dana J. Boente  
Acting United States Attorney

By:   
Lindsay A. Kelly  
Assistant United States Attorney



**OFFICER'S CERTIFICATE**

I hereby agree that I have consulted with my attorney and fully understand all rights with respect to the pending criminal Indictment. Further, I fully understand all rights with respect to Title 18, United States Code, Section 3553 and the provisions of the Sentencing Guidelines Manual that may apply in my case. I have read this plea agreement and carefully reviewed every part of it with my attorney. I understand this agreement and voluntarily agree to it on behalf of GALLANT PHARMA INTERNATIONAL, INC. ("GALLANT PHARMA").

I am also satisfied with counsel's representation in this matter. In addition, despite any potential or actual conflict of interest which may exist now or in the future, GALLANT PHARMA hereby consents to the simultaneous representation by Womble Carlyle Sandridge and Rice LLP (including but not limited to its attorneys Mark Schamel and Lela Ames) of GALLANT PHARMA and Syed Huda (a/k/a "Farhan Huda"), with respect to the matters covered in this Statement of Facts and Plea Agreement.

I certify that I am President and a Director of GALLANT PHARMA and am duly authorized to execute this Agreement on behalf of GALLANT PHARMA.

Date: 12/6/13

  
\_\_\_\_\_  
Syed Huda,  
GALLANT PHARMA INTERNATIONAL INC.  
President and Director

**CERTIFICATE OF COUNSEL**

I am GALLANT PHARMA INTERNATIONAL INC.'s ("GALLANT PHARMA") attorney. I have carefully reviewed the above Plea Agreement with my client. In connection with such representation, moreover, I have examined the relevant documents and have discussed the terms of this Agreement with GALLANT PHARMA's authorized representative. Based on our review of the foregoing materials and discussion, I am of the opinion that this Agreement has been duly and validity authorized, executed, and delivered on behalf of GALLANT PHARMA and is a valid and binding obligation of GALLANT PHARMA. To my knowledge, the decision of GALLANT PHARMA to enter into this Agreement is an informed and voluntary one.

Date:

12/02/13



Mark Schamel, Esquire

Counsel for GALLANT PHARMA INTERNATIONAL INC.